REMARKS

Applicants have studied the Office Action mailed January 24, 2005. It is respectfully submitted that the application is in condition for allowance. Reconsideration and allowance of the pending claims in view of the following remarks is respectfully requested.

Rejection of claims 4, 8-9, and 24-29 under 35 USC §101 and §112, 1st paragraph:

The Examiner rejected claims 4, 8-9, and 24-29 under 35 U.S.C. §101 and §112, 1st paragraph, because the claimed invention is not supported by either a specific, substantial, credible asserted utility or a well established utility and, consequently, one skilled in the art would not know how to make/use the claimed invention.

In making these rejections, the Examiner states, in part, that the instant specification does not teach any physiological ligands or functional characteristics of the GPCR set forth in SEQ ID NO:2 or encoded by the disclosed nucleic acid set forth in SEQ ID NOs:1 and 3, and that there is no well-established utility for a specific nucleic acid or amino acid sequence and the specification fails to disclose a specific and substantial utility for the claimed invention. The Examiner lists 14 utilities asserted in the specification for the claimed DNA, and states that these asserted utilities are neither specific nor substantial because they do not identify or reasonably confirm a "real world" context of use. The specification neither identifies the biological functions of the claimed protein and DNA, nor any diseases that are associated with the claimed molecules, and without any biological activity or link to a disease, such constitutes further research to determine the properties of the claimed GPCR protein or partial peptides, which is insufficient to meet the requirements of 35 U.S.C. §101. The Examiner states that these activities and functions are conjectural and are based solely on the identification of the putative protein of SEQ ID NO:2 as being a GPCR, and that, while it is credible that SEQ ID NO:2 is a GPCR, its identification as such is not sufficient to establish either a well known, or a specific, substantial, and credible utility. There is no ligand identified that binds to it, no signaling pathway with which it is involved, and no disease or disorder correlated with the polypeptide. The Examiner further states that the art teaches that the GPCR family is extremely diverse, and that function cannot be predicted merely by identifying a protein as a GPCR. The Examiner states that, thus, although the homology of the GPCR family, especially in the transmembrane domain regions, allows

identification of such as GPCRs, mere homology and quantification of gene expression is not accepted by those of skill in the art as being predictive of function. The Examiner concludes by stating that the instant claims are drawn to a protein which has undetermined function or biological significance, and until some actual and specific activity or significance can be attributed to the protein identified in the specification as SEQ ID NO:2 or the polynucleotide encoding it (SEQ ID NOs:1 and 3), the claimed invention is incomplete.

Applicants respectfully traverse these rejections based on the following remarks.

The function of GPCRs in general is to direct signal transduction within a cell. Upon binding of a ligand to the extracellular portion of a GPCR, a signal is transduced within the cell that results in a change in a biological or physiological property of the cell. GPCRs are part of the modular signaling system that connects the state of intracellular second messengers to extracellular inputs. Such functions are quite specific for the family of GPCR proteins and differentiate them from other types of proteins. As such, this function is specific enough to define uses for novel GPCR proteins, such as in the drug discovery process.

Even so, Applicants have even further characterized the protein of SEQ ID NO:2 (which is encoded by the claimed nucleic acid molecules) as a Mas-related GPCR. Membership in the subfamily of Mas-related GPCRs is even more specific than membership in the family of GPCR proteins and clearly imparts a specific and substantial utility to the claimed nucleic acid molecules. Given the guidance provided in the specification and figures in combination with the knowledge in the art regarding the known biological roles of known Mas-related GPCRs, one of ordinary skill in the art would know how to use the claimed nucleic acid molecules (which encode novel Mas-related GPCRs) provided by Applicants without undue experimentation.

The functions and disease associations of Mas-related GPCRs are well known in the art. For example, Mas-related GPCRs exert oncogenic effects such as by modulating critical components of cell signaling and growth-regulating pathways, and are therefore associated with cancer. Thus, the discovery of a new Mas-related GPCR satisfies a need in the art by providing new compositions which are useful towards, for example, the prevention, diagnosis, and treatment of cancer. Thus, the polypeptide of SEQ ID NO:2 and the encoding nucleic acid molecules are associated with specific disorders and are therefore supported by specific and substantial utilities.

In characterizing the protein of SEQ ID NO:2 as a GPCR protein, particularly a Mas-related GPCR, Applicants have collectively considered multiple independent lines of evidence, in

addition to sequence homology to known GPCR proteins. All the available evidence consistently and unambiguously supports the function and utility of the protein of SEQ ID NO:2 as a GPCR protein, particularly a Mas-related GPCR. For example, the results of the analysis of membrane spanning structure and domains, provided on page 1 of Figure 2, indicates the presence of 7 transmembrane domains, which is a signature characteristic of GPCR proteins, and each of the 7 transmembrane domains is characterized as "Certain" with respect to degree of confidence. Further, page 1 of Figure 2 also provides Prosite analysis of functional domains and key regions, which indicates the presence of a GPCR family 1 signature. Moreover, the top BLAST hits shown on pages 1-2 of Figure 1 demonstrate that the proteins that share the highest degree of amino acid sequence similarity to SEQ ID NO:2 are Mas-related GPCRs (the amino acid sequence alignment of the top BLAST hit compared to SEQ ID NO:2 is shown on page 2 of Figure 2).

One of ordinary skill in the art would recognize that novel Mas-related GPCRs and encoding nucleic acid molecules, such as those of the instant claims, have specific and substantial utilities that meet the requirements of 35 U.S.C. §101 and §112, 1st paragraph. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw these rejections.

Conclusions

Claims 4, 8-9, and 24-29 remain pending.

In view of the above remarks, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the objections and rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent at (240) 453-3812 should the Examiner believe a telephone interview would advance prosecution of the application.

Respectfully submitted,
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